PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1142 KW 11-1-95

In re Application of: §
J. M. Steinke §
A.P. Shepherd § Examiner: K. Hantis
§
Serial No.: 07/953,680 §
§ Group Art Unit: 2505
Filed: September 29, 1992 §
§
For: METHOD AND APPARATUS § Atty. Dkt.: UTSK:142/BAH #17 1/2
FOR DIRECT SPECTROPHOTO- §
METRIC MEASUREMENTS IN §
UNALTERED WHOLE BLOOD §

CERTIFICATE OF MAILING
37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231, on the date below:

October 10, 1995 — David D. Bahler
Date **David D. Bahler**

SUPPLEMENTAL DECLARATION OF JOSEPH M. SCHMITT
UNDER 37 C.F.R. § 1.132

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

I, JOSEPH M. SCHMITT, hereby declare and state:

1. I am the same Joseph M. Schmitt who signed the Declaration Under 37 C.F.R. § 1.132 on February 25, 1994, that was filed in support of the above-identified application on April 24, 1994. Attached to this Declaration is an updated version of my *Curriculum Vitae*, which summarizes my education and employment, and which includes an updated listing of my publications.

2. I have read the following documents:

a. The above-identified patent application including pending claims 1-36;

b. The Office Action mailed by the United States Patent and Trademark Office on April 26, 1995;

c. Anderson and Sekelj, "Light-Absorbing and Scattering Properties of Non-Haemolysed Blood," *Phys. Med. Biol.*, 12(2):173-184, 1967;

d. Brown *et al.*, U.S. Patent No. 4,134,678;

e. Curtis, U.S. Patent No. 5,064,282.

3. It is my understanding that the Examiner continues to reject claims of the above-identified patent application based upon the teachings of Anderson *et al.*, and now rejects claims of the application based upon the teachings of Anderson *et al.* in combination with Brown *et al.*. I also understand that the Examiner relies upon the disclosure of Curtis to reject claims in this application. In my opinion, as presented in more detail below, none of these rejections is well-founded.

4. Turning first to the Anderson *et al.* reference, disclosed is that the difference in total optical attenuation before and after hemolysis of a particular suspension of red blood cells in isotonic saline is an estimate of the magnitude of light scattering before that particular blood cell suspension was hemolyzed. However, as shown in curve C in Figure 6 of Anderson *et al.*, the magnitude of light scattering varies with total hemoglobin concentration. In a practical application, the hemoglobin concentration of a sample under test is completely unknown. Thus,

the only way to use Anderson *et al.* to "correct" for the effects of scattering, as suggested by the Examiner (see, for example, Office Action of 4/26/95 at page 6), is to first measure the total hemoglobin concentration of a sample under test by some independent method. This prior measurement would thus render any sort of measurement by the apparatus disclosed in Anderson *et al.* completely superfluous, and thus useless. In addition, this prior measurement would render the sample of "known" composition -- contrary to a requirement of the present invention that measurements be made on whole unaltered blood of unknown composition.

5. Even if one were to measure total hemoglobin concentration of each unknown sample by some independent method, as would be required to apply Anderson *et al.* to a practical application, the Examiner's "correction" still would not work, as the examples in the following paragraphs show.

6. First, Anderson *et al.* use non-hemolyzed red blood cells suspended in saline when conducting their observations. In particular, Anderson *et al.* state in the first full paragraph on page 177 that "fully oxygenated non-haemolyzed red cells suspended in isotonic saline were studied." Moreover, each of the graphs depicted in the Anderson *et al.* article, with the exception of Figure 5, expressly state that what was being studied were "red-cell suspensions," and it is quite likely that the measurements depicted in Figure 5 were also taken from red-cell suspensions. In addition, only oxygenated blood is being considered, which is but

one species of hemoglobin existing in unaltered whole blood. Thus Anderson *et al*. measure only altered blood of known composition, in contrast to the invention of the above-identified application.

7. The light scattering characteristics of red blood cells suspended in saline would be completely different from those of the unaltered whole blood measured by the present invention. Such unaltered whole blood includes red blood cells suspended in plasma which includes many things other than red blood cells.

8. For example, the plasma protein concentration greatly affects the amount of scattering by red blood cells suspended in plasma because the refractive index of plasma depends on its protein concentration. Because the amount of light scattering depends on the difference between the refractive indices of plasma and red cells, the magnitude of the light scattering in an unknown sample would be different from what it was when any sort of "correction" run occurred. Consequently, the magnitude of the light scattering estimated by the previously established "correction" would not yield a valid estimate of scattering, and all subsequent computations would be nonsense.

9. Second, different hemoglobin species in the blood affect the amount of the light absorbance and scattering. For example, if the "correction" were established with blood composed of 90% oxyhemoglobin and 10% deoxyhemoglobin, the previously established "correction" would not yield a valid measure of light scattering if the unknown sample contained 75% oxyhemoglobin because light scattering depends on the actual chemical composition of the blood.

The dependence of light scattering on the chemical composition of the blood was completely unknown to Anderson *et al.*, whereas Figures 4 and 5 of the present application teach composition-dependence of the red blood cell scattering vector and the nonspecific scattering vector. Thus, in the case in which the chemical composition of the blood varies (in reality, a very common occurrence), the "correction" method suggested by the Examiner would completely fail.

10. Third, if chylomicrons and other lipid droplets are present in the plasma, these also scatter light, thus rendering the "correction" method suggested by the examiner completely useless. By contrast, the inclusion of chylomicrons and other lipid droplets in plasma (once again a normal occurrence), causes only minimal interference in measurements made by the present invention.

11. Fourth, if the sample used to create the "correction" had a hemoglobin concentration <u>within</u> the red blood cells that is different from the sample presently under consideration, the "correction" method suggested by the Examiner would fail to yield a valid estimate of light scattering by red blood cells because the refractive index of the red blood cells depends on the <u>intracellular</u> hemoglobin concentration. Once again, the present invention is capable of accurately determining the concentrations of a plurality of blood components despite differing intracellular hemoglobin concentration.

12. As a fifth example of the failings of the "correction" method suggested by the Examiner, consider the case of red blood

cells that differ from normal in their size and shape. Spherocytosis, osmotically swollen red blood cells, and sickle cell anemia are specific clinical conditions in which such changes occur. If the Examiner's "correction" had been established for normal blood, it would yield specious estimates of the magnitude of light scattering because light scattering by red blood cells depends on their size and shape. Again, the use of the "correction" method suggested by the Examiner would fail miserably.

13. Sixth, consider the case in which a substantial fraction of the red blood cells in the clinical sample are hemolyzed. The erroneous "correction" established in the manner suggested by the Examiner would reflect the light scattering only when all of the red blood cells in the reference blood are intact. Therefore, the Examiner's "correction" would fail to yield a valid measurement of light scattering when some unknown fraction of the red blood cells or all of the red blood cells were ruptured. Again, all subsequent computations would be grossly erroneous. By contrast, the present invention yields valid measurements both when the red blood cells in the blood samples are intact and when they are completely hemolyzed (page 40, Table IV of the present application).

14. The foregoing examples illustrate the sample-to-sample variation in light scattering that commonly occur in clinical blood samples. To anyone of ordinary skill in this technology, each single example is convincing proof that using Anderson *et al.*, either alone or in combination with Brown *et al.*, as the Examiner proposes, would not yield a functional device capable of measuring

the concentrations of multiple "components of unaltered whole blood" as required by independent claim 1. Furthermore, in each of the foregoing examples, using Anderson *et al.* as a "correction" in the ill-defined manner suggested by the Examiner would require measuring the total hemoglobin concentration by some independent method, and even then the quantity obtained would be a constant that would not reflect the true magnitude of light scattering in the blood sample at hand.

15. In contrast, the invention of the above-identified application computes concentrations of the components of whole unaltered blood of unknown composition through the use of a scattering subset of radiation wavelengths that are used to correct for the effects of radiation scattering from red blood cells and from other scattering factors existing in unaltered blood.

16. The Brown *et al.* reference does not supply any of the above-noted discrepancies existing in the Anderson *et al.* reference. In particular, the Brown *et al.* reference presents multi-wavelength spectrophotometry which uses one wavelength for each blood component to be determined (see Figure 5 and col. 3, lines 31-39). Thus, the only set of wavelengths contemplated by Brown *et al.* is a set of absorbance wavelengths, and there is no disclosure or suggestion of a set of scattering wavelengths, as required by the present invention.

17. In fact, the only scattering correction contemplated by Brown *et al.* is accomplished by hemolyzing the blood sample before optical measurements are made. See col. 6, lines 41-43; col. 8,

lines 2-7 and 21-22; col. 10, lines 8-9; col. 13, lines 55-68; col. 14, lines 16-17; col. 15, line 43; col. 16, lines 8 and 40; col. 17, line 6 and 37, and col. 18, lines 9 and 36-37.

18. Thus, Anderson *et al.* contemplate measurement of altered blood in the form of a red cell suspension which suspends nonhemolyzed red blood cells in isotonic saline, whereas Brown *et al.* require hemolysis and dilution of whole blood, before optical measurements. Neither Brown *et al.* nor Anderson *et al.*, either alone or in combination, make measurements on whole unaltered blood, as required by the present invention.

19. In fact, if an apparatus embodying the Brown *et al.* invention were to have the hemolyzer disabled, completely erroneous results would occur, similar to the erroneous results depicted in the comparative example appearing in the present patent application on pages 38-41.

20. I also understand that the Examiner relies upon the teachings of Curtis *et al.* reference to reject claims in the present application. In my opinion, reliance upon the teachings of Curtis *et al.* to reject claims in this application is totally unfounded. In particular, Curtis *et al.*, like Anderson *et al.* and Brown *et al.*, require alteration of the blood sample, before optical measurements are made in order to reduce the effects of light scattering present in whole unaltered blood. In particular, Curtis hemolyzes the blood with a lysing agent which breaks up the red blood cells to release hemoglobin into solution. See col. 2, lines 4-6 and col. 5, lines 45-52.

21. In addition, Curtis does not disclose an absorbance subset of wavelengths distinct from a scattering subset of wavelengths, as required by the present invention. In particular, Curtis sought two wavelength passbands for which oxyhemoglobin and deoxyhemoglobin have approximately equal absorptivity deltas (average absorptivity at passband 1 minus average absorptivity at passband 2 being approximately the same for oxy- and deoxyhemoglobin). His goal was to measure total hemoglobin concentration using only the difference in absorbance at two wavelength passbands; therefore, he was forced to seek the same delta for oxyhemoglobin and deoxyhemoglobin so that the answer he obtained for hemoglobin concentration did not depend much on the state of oxygenation of the sample. There is absolutely no disclosure or suggestion in Curtis of a scattering subset of wavelengths of any kind, much less a scattering subset of wavelengths that have been "selected to maximize the effects of radiation scattering by unaltered whole blood relative to the effects of radiation absorbance by unaltered whole blood."

22. In conclusion, the prior art references of which I am aware, including references c-e mentioned above in paragraph 2, do not teach one of ordinary skill in this technology, and do not teach me personally, how to make and use the invention disclosed and claimed in the above-identified patent application. Further, even in view of the scope and content of the disclosure of the prior art, the invention as claimed in the present patent application, as a whole, would not have been obvious at the time

the invention was made to a person having ordinary skill in this art.

23. I hereby declare that all of the statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application, or any patent issuing therefrom.

July 10, 1995
Date

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Ph.D., electrical engineering, March 1986

M.S., electrical engineering, March 1983

Case Western Reserve U.
Cleveland, OH

B.S., biomedical engineering/ pre-med., May 1981; (Highest Honors)

Employment:

9/94-present

Associate Professor
Electrical and Electronic Engineering Department
Hong Kong University of Science and Technology
Clear Water Bay, Kowloon, Hong Kong

Responsible for establishing a biomedical electronics program with a both research and teaching components.

Consultant -- Research and Development

12/94-present

Boehringer-Mannheim Corporation
New Technology Division
Mannheim, Germany

Carry out feasibility studies on a variety of topics, including new forms of microscopy and methods for monitioring optical glucose monitoring *in vivo*.

5/93-9/94

Nellcor, Inc.
Hayward, CA 94545

Designed and recommended methods for fetal monitoring by pulse oximetry.

7/88-9/94 Senior Staff Fellow
Lasers and Modern Optics Group
Biomedical Engineering and Instrumentation Program
National Institutes of Health, Bethesda, MD

Co-founded a laboratory dedicated to the development of non-invasive technologies for medical diagnostic applications.

Consultant -- International Development

2/93 -3/93 Project HOPE
Shanghai, China

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4/86-5/86 Project HOPE
Kingston, Jamaica

Trained biomedical engineering technicians and engineers in developing countries in cooperation with national health ministries.

5/86- 5/88 Biomed. Engin. Coordinator
Project HOPE, Zhejiang Medical University
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Developed biomedical engineering and technician training programs in medical schools. My efforts were part of a long-term plan to modernize the technological capabilities of hospitals in mainland China.

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PUBLICATIONS (in reverse chronological order)

Journal Articles

J.M. Schmitt and K. Ben-Letaief, "Efficient Monte-Carlo Simulation of Confocal Microscopy in Biological Tissue," *J. Opt. Soc. Am. A* , submitted June 1995.

M. Yadlowsky, J.M. Schmitt, and R.F. Bonner, "Multiple Scattering Effects in Optical Coherence Microscopy," *Applied Optics*, in press.

J.M. Schmitt, M. Yadlowsky, and R.F. Bonner, "Subsurface Imaging of Living Skin with Optical Coherence Microscopy," *Dermatology*, in press.

J.M. Schmitt, "Compact In-line Interferometor for Low-Coherence Interferometry," *Optics Lett.*, 20 (4), 1995, 419-421.

J.M. Schmitt, A. Knüttel, and M. Yadlowsky, " Optical Coherence Tomography of a Dense Tissue: Statistics of Attenuation and Backscattering," *Phys. Med. Biol.*, 39, 1994, 1705-1720..

J.M. Schmitt, A. Knüttel, and M. Yadlowsky,"Confocal Microscopy in Turbid Media," *J. Opt. Soc.Am. A* , 11, 1994, 2226 -2235.

D. Bicout, C. Brosseau, A.S. Martinez, and J.M. Schmitt, "Depolarization of Multiply Scattered Waves by Spherical Diffusers: Influence of the Size Parameter," *Phys. Rev. E* , 49 , 1994, 1767-1770.

A. Knüttel, J.M. Schmitt, and J.F. Knutson,"Low-Coherence Reflectometry for Stationary Lateral and Depth Profiling Using Acousto-Optic Deflectors and a CCD Camera," *Optics Lett.*, 19, 1994, 302-304.

J.M. Schmitt, A. Knüttel, and R.F. Bonner, "Measurement of Optical Properties of Biological Tissues by Low-Coherence Reflectometry," *Applied Optics*, 32 , 1993, 6032-6042.

A. Knüttel and J.M. Schmitt, "Stationary Depth-Profiling Reflectometer Based on Low-Coherence Interferometry," *Optics Commun.*, 102, 1993, 193-198.

G.X. Zhou, J.M. Schmitt, and E.C. Walker, "An Electro-Optic Simulator for Pulse Oximeters," *Med. Biol. Eng. & Comput.* , 31, 1993, 534-539.

G.X. Zhou, J.M. Schmitt, and C.E. Ellicott, "Sensitive Detection of Optical Rotation in Liquids by Reflection Polarimetry, " *Rev. Sci. Instr.*, 64 , 1993 , 2801-2807.

A. Knüttel, J.M. Schmitt, and J.F. Knutson,"Acousto-Optic Scanning and Interfering Photon Density Waves for the Precise Localization of an Absorbing (or Fluorescent) Body in a Turbid Medium," *Rev. Sci. Instrum.*, 64, 1993, pp. 638 - 644.

A. Knüttel, J.M. Schmitt, and J.F. Knutson,"Spatial Localization of Absorbing Bodies by Interfering Diffusive Photon-Density Waves," *Applied Optics*, 32, 1993, pp. 381 - 389.

J.M. Schmitt, A. Knüttel, and J.R. Knutson, "Interference of Diffusive Light Waves," *J. Opt. Soc. Am. A*, 9, 1992, pp. 1832- 1843; Reprinted in : Milestones Series on Tissue Optics, Vol. MS 102, (SPIE Optical Engineering Press, Bellingham, WA) 1994.

J.M. Schmitt, A.H. Gandjbakhche, and R.F. Bonner, "Use of Polarized Light to Discriminate Short-Path Photons in a Multiply Scattering Medium ," *Applied Optics*, 31, 1992, pp.6535-6546; Reprinted in : Milestones Series on Tissue Optics, Vol. MS 102, (SPIE Optical Engineering Press, Bellingham, WA) 1994.

J.W. Peabody and J.M. Schmitt, "Medical Equipment in the People's Republic of China. A Survey of Medical Equipment Procurement, Utilization, and Maintenance in University-Affiliated Hospitals Between 1976 and 1987, *Int. J. Tech. Assess. in Health Care*, 8, 1992, pp. 138-149.

N.V. Bergasa , T.L. Talbot, D. Alling, J.M. Schmitt, E.C. Walker,B. Baker, J.C. Korenman, Y. Park, J.H. Hoofnagle, and E.A. Jones, "A Controlled Trial of Naloxone Infusions for the Pruritis of Chronic Cholestasis," *Gastroenterology*, 102, 1992, pp. 544 - 559.

J.M. Schmitt, "Simple Photon Diffusion Analysis of the Effects of Multiple Scattering on Pulse Oximetry," *IEEE Trans. Biomed. Eng.*, 38(12), 1991, pp. 1194-1203.

T.L. Talbot, J.M. Schmitt, N.V. Bergasa, E.A. Jones, and E.C. Walker, "Application of Piezo Film Technology for the Quantitative Assessment of Pruritus," *Biomed. Instr. and Tech.*, 25, 1991, pp. 400 -403.

J.M. Schmitt, R.L. Webber, and E.C. Walker, "Optical Determination of Dental Pulp Vitality, *I EEE Trans. Biomed. Engin.* , 38 (4), 1991, pp. 346 - 352.

JM. Schmitt, G.X. Zhou, E.C. Walker, and R.T. Wall, "Multi-layer Model of Photon Diffusion in Skin," *J. Opt. Soc. Am. A* , 7 (11), 1990, pp. 2141-2153.

J.M. Schmitt and H. Al-Fadel, "Design of Medical Instrumentation for Applications in Developing Countries," *J. Clin. Engin.*, 14 (4), 1989, pp. 299-306.

J.M. Schmitt, F.G. Mihm, and J.D. Meindl, "New Methods for Whole Blood Oximetry," *Annals of Biomed. Eng.*, 14, 1986, pp. 35-52.

J.M. Schmitt, J.D. Meindl, and F.G. Mihm, "An Integrated-Circuit-Based Optical Sensor for In Vivo Measurement of Oxygen Saturation, " *IEEE Trans. Biomed. Eng.*, 33, 1986, pp. 98-107.

J.M. Schmitt, M. Baer, M.F. Anderson, F.G. Mihm, and J.D. Meindl, "Inhibition of Thrombus Formation on Intravascular Sensors by Electrical Polarization, " *J. Biomed. Mater. Res.*, 18, 1984, pp. 797-807.

Books and Book Chapters

J.M. Schmitt, "Plethysmography," to be included in the *Encyclopedia of Scientific Instrumentation* (commissioned by the American Chemical Society).

J.M. Schmitt, D. Harame, and L. Bousse, "Implantable Chemical Sensors for Blood Gas Analysis," in Methods of Animal Experimentation (Vol. VII) (W.I. Gay and J.E. Heavner, eds.), Academic Press, New York, 1986, pp. 67-71.

L. Bowman, J.M. Schmitt, and J.D. Meindl, "Electrical Contacts to Implantable Integrated Sensors

by CO_2 Laser-Drilled Vias in Glass, " in Micromachining and Micropackaging of Transducers (C.D. Fung, P.W. Cheung, W.H. Ko, and D.G. Fleming, eds.), Elsevier Press, New York, 1985, pp. 79-84.

Optical Measurement of Blood Oxygen by Implantable Telemetry, Ph. D. Thesis, Stanford University, Dept. of Electrical Engineering, March 1986.

Proceedings Papers

M. Yadlowsky, J.M. Schmitt, and R.F. Bonner, "Contrast and Resolution in the Optical Coherence Microscopy of Dense Biological Tissue," *Proc. SPIE*, 2387, 1995, 193-203.

J.M. Schmitt, A. Knüttel, and M. Yadlowsky, "Low-coherence interferometry for imaging microstructures within optically turbid tissues," OSA Proc. on Adv. Optical Imaging and Photon Migration, 21,1994, 253-256.

J.M. Schmitt, A. Knüttel, and M. Yadlowsky, "Interferometric Versus Confocal Techniques for Imaging Microstructures in Turbid Biological Media ," *Proc. SPIE* , 2135, 1994, 251-262 .

J.M. Schmitt, A. Knüttel, A. Gandjbakhche, and R.F. Bonner, "Optical Characterization of Dense Tissues Using Low-Coherence Interferometry, " *Proc. SPIE*, 1889, 1993, pp197-211.

A. Knüttel, J.M. Schmitt, R. Barnes, and J.R. Knutson, "Spatial Localization Using Photon-Density Waves: Contrast Enhancements and Limitations, " *Proc. SPIE* , 1888, 1993 ,322-333.

A.H. Gandjbakhche, J.M. Schmitt, R. Bonner, and R. Nossal, "Random Walk Theory Applied to Noninvasive In Vivo Optical Measurements of Human Tissue," *Proc. 14th Annual Intern. Conf. IEEE EMBS*, Paris , France, Oct. 29-Nov. 1, 1992, pp. 332-333.

A. Knüttel, J.M. Schmitt, and J. Knutson, "Improvement of Spatial Resolution in Reflectance Near-IR Imaging by Laser-Beam Interference, " *Proc. SPIE* , 1640 , 1992, pp. 405- 416.

J.M. Schmitt, G.X. Zhou, and J. Miller, "Measurement of Blood Hematocrit by Dual-Wavelength Near-IR Photoplethysmography, " *Proc. SPIE* , 1641, 1992, pp. 150-161.

R. Nossal and J.M. Schmitt, "Measuring Photon Path Lengths by Quasielastic Light Scattering in a Multiply Scattering Medium,"*Proc. SPIE* , 1430,1991, pp. 37-47.

G.X. Zhou, J.M. Schmitt, L. Eldridge, and E.C. Walker, "Pulse Oximeter Calibrator Based on a Liquid-Crystal Light Valve," *Proc. 12th Ann. IEEE Engin. in Med. Biol. Soc. Conf.*, 12(5),1990, pp. 2012-2013.

J.M. Schmitt and Dai Rong-Qing, "Requirements for Clinical Biomedical Engineering Development (in Chinese)," *Proc. Zhejiang Univ. Biomed. Eng Soc. Meeting*, Hangzhou, P.R.C., Sept. 1987, pp.132-136.

J.M. Schmitt, J.D. Meindl, and J. Shott, "Implantable Telemetry for Measurement of O_2 Saturation," *Proc. IEEE Frontiers of Eng. and Comp. in Health Care*, Los Angeles, CA, Sept. 1984, pp. 703-707.

Patents

J.M. Schmitt, E.C. Walker, and R.L. Webber, "Pulse Oximeter for Diagnosis of Dental Pulp Pathology" (U.S. Pat.07/350,908).

(Pending) J.M. Schmitt, "Optical Method for Monitoring Arterial Blood Hematocrit" (U.S. Pat. Appl. 07/822,018).

(Pending) J.R. Knutson, A. Knüttel, and J.M. Schmitt, "Differential Diffusive Waves: Optical Frequency Modulation-Diffusive Wave Detection Methods for Localization and Spectroscopy of Objects inside Turbid Media."